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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,049	07/12/2006	Osvaldo L. Podhajcer	15138-003US1	6069

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MINNEAPOLIS, MN 55440-1022

EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
09/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,049	PODHAJCER ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2010*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47,48,50,52-67,86 and 87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *47, 48, 50, 52-67 and 86-87* _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on *07/21/2010* in response to office action mailed on 01/21/2010 has been acknowledged.

Claims 47, 48, 50, 60-61 are amended.

Claim 51 is canceled.

Claim 87 is new.

Claims 1-46, 49, 51 and 68-85 were previously cancelled.

Claims 47, 48, 50, 52-67 and 86-87 are pending.

Applicant's amendments to claims after previous Election/Restriction *and the scope and nature of the amended subject matter are such that, the claims require a further restriction.*

37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. Exparte Benke, 1904C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904).

The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

Claims 47, 48, 50, 52-67 and 86-87 are under Election/Restriction.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions as claimed are classified into following groups:

I. Claims 47, 48, 50, 53-56, 60-64 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of protein in the sample wherein the protein is selected from subgenus of proteins recited in claim 50 and the match indicating the subject has or will develop the non CNS-disorder..

II. Claims 47, 48, 52, 53-56, 60-64 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of protein in the sample wherein the protein species is selected from specific proteins recited in claim 52 and the match indicating the subject has or will develop the non CNS-disorder.

III. Claims 47, 48, 53-56, 57-59, 60-64, 86 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of protein in the sample wherein the gene encodes a protein species for **breast cancer** selected from specific gene products for breast cancer recited in claim 86 and the match indicating the subject has or will develop the non CNS-disorder.

IV. Claims 47, 48, 53-56, 57-59, 60-64, 86 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of protein in the sample wherein the gene encodes a protein species for **colon cancer** selected from specific gene products for colon cancer recited in claim 86 and the match indicating the subject has or will develop the non CNS-disorder.

V Claims 47, 48, 53-56, 57-59, 60-64, 86 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of protein in the sample wherein the gene encodes a protein species for **Lung cancer** selected from specific gene products for lung cancer recited in claim 86 and the match indicating the subject has or will develop the non CNS-disorder.

VI. Claims 47, 48, 53-56, 57, 60-64, 86 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of protein in the sample wherein the gene encodes a protein species for **arthritis** selected from specific gene products for arthritis recited in claim 86 and the match indicating the subject has or will develop the non CNS-disorder.

VII. Claims 47, 48, 53-56, 57, 60-64, 86 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of protein in the sample wherein the gene encodes a protein species for **asthma** selected from specific gene products for asthma recited in claim 86 and the match indicating the subject has or will develop the non CNS-disorder.

VIII. Claims 47, 48, 53-56, 60-64, 65 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of a protein in the sample of a subject wherein the subject lacks a clinical sign of a disorder as evaluated by imaging analysis and the match indicating the subject has or will develop the non CNS-disorder.

IX. Claims 47, 48, 53-56, 60-64, 66-67 and 87 drawn to a method of diagnosing a non-central nervous system (CNS) disorder and detecting expression of a gene in CNS and comparing gene expression profile that corresponds to level of a protein in the sample of a subject wherein the subject is a carrier of gene associated with increased risk of developing the disorder and the match indicating the subject has or will develop the non CNS-disorder.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a) a prior art of

record exists regarding a feature linking technical claims correlation of expression profile of CNS and Non-CNS expression in diagnosing cancer (For example see; Petricoin et al., Lancet 2002, 359:572-577; Cleland et al 2003, Cancer 97:2919-2925; WO/2002/24956). The invention as a whole thus lacks unity under PCT rule hence a restriction as indicated above is proper. The mode of operation, and the effects evaluated in each of the above invention are distinct and different from the other. Therefore, a search and examination for the patentability of the above inventive groups together would generate an undue search burden on the examiner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between sub-combinations usable together. Where applicant elects a sub-combination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable sub-combination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting

rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to the following patentably distinct species: Should Group I be elected from above, the.

(a). Applicant is required chose a single subgenus of proteins among the recited in claim 50 i.e., a hormone or a growth factor or an immune system component or a cytokine.

(b). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(c). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain.

This application contains claims directed to the following patentably distinct species: Should Group II be elected from above, the.

(a). Applicant is required chose a single species of a gene product encoded by the gene recited in claim 52 i.e., hepatocyte growth factor (HGF) or apherin A3 or chemokine (C-Cmotif) ligand 4 or growth differentiation factor-9b (GDF-9b) or bone morphogenetic protein 15 (BMP 15) or neuroblastoma suppressor of tumorigenicity 1 or melanocyte proliferating gene 1 or fibroblast growth factor 22 (FGF 22).

(b). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(c). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain.

This application contains claims directed to the following patentably distinct species: Should Group III be elected from above, the.

(a). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(b). Applicant is required chose a single species of non-CNS disorders among the disorders recited in claims 57 i.e., cancer or rheumatoid arthritis or asthma or diabetes or obesity.

(c). Applicant is required chose a single species of gene encoding gene product for breast cancer among the recited in claim 86.

(d). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain.

This application contains claims directed to the following patentably distinct species: Should Group IV be elected from above, the.

(a). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(b). Applicant is required chose a single species of non-CNS disorders among the disorders recited in claims 57 i.e., cancer or rheumatoid arthritis or asthma or diabetes or obesity.

(c). Applicant is required chose a single species of gene encoding a gene product for colon cancer among the recited in claim 86.

(d). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain.

This application contains claims directed to the following patentably distinct species: Should Group V be elected from above, the.

(a). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(b). Applicant is required chose a single species of non-CNS disorders among the disorders recited in claims 57 i.e., cancer or rheumatoid arthritis or asthma or diabetes or obesity.

(c). Applicant is required chose a single species of gene encoding gene product for lung cancer among the recited in claim 86.

(d). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain.

This application contains claims directed to the following patentably distinct species: Should Group VI be elected from above, the.

(a). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(b). Applicant is required chose a single species of non-CNS disorders among the disorders recited in claims 57 i.e., cancer or rheumatoid arthritis or asthma or diabetes or obesity.

(c). Applicant is required chose a single species of gene encoding gene product for arthritis among the recited in claim 86.

(d). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain.

This application contains claims directed to the following patentably distinct species: Should GroupVII be elected from above, the.

(a). Applicant is required chose a single species of non-CNS disorders among the disorders recited in claims 57 i.e., cancer or rheumatoid arthritis or asthma or diabetes or obesity.

(b). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(c). Applicant is required chose a single species of gene encoding gene product for asthma among the recited in claim 86.

(d). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain.

This application contains claims directed to the following patentably distinct species: Should GroupVIII be elected from above, the.

(a). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(b). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain

This application contains claims directed to the following patentably distinct species: Should Group IX be elected from above, the.

(a). Applicant is required chose a single species of brain cells among the recited in claims 54 i.e. the hypothalamus or the midbrain or the prefrontal cortex or the striatum.

(b) Applicant is required chose a single species of carrier gene associated disorders among the recited in claims 67 i.e., BRCA1 or BRCA2 or hMSH2 or hMLH1 or hMSH6.

(d). Applicant is required chose a single species of cell among the recited in claims 87 i.e. a cell the brain of the subject or cell from spinal cord of the subject or cerebrospinal fluid (CSF).

The species are independent or distinct because they are structurally distinct .and/or involved in different functional aspects of brain

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at (571) 272-0739. The fax phone number for the organization where this application or

proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633